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PATENT

Attorney Docket No. VENPRO.007C1

Date: June 28, 2000

Page

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ASSISTANT COMMISSIONER FOR PATENTS

WASHINGTON, D.C. 20231

ATTENTION: BOX PATENT APPLICATION

Sir:

Transmitted herewith for filing is the patent application of

Inventor(s): **Rodolfo C. Quijano and Robert Loya**For: **A BIFURCATED BIOLOGICAL PULMONARY VALVED CONDUIT**

Enclosed are:

- (X) Specification in twelve (12) pages.
- (X) Three (3) sheets of drawings.
- (X) Initial signed declaration by inventor(s).
- (X) Return prepaid postcard.
- (X) This application is a continuation of prior application 09/252,333, filed February 18, 1999.
- (X) A copy of Declaration from prior application is enclosed.
- (X) Preliminary Amendment is enclosed.
- (X) A small entity statement was filed in the prior application, and such status is still proper and desired.
- (X) Incorporation by Reference. The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

CLAIMS AS FILED

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Independent Claims	1 - 3 =	0 ×	\$39	\$0
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TOTAL FILING FEE			\$345	

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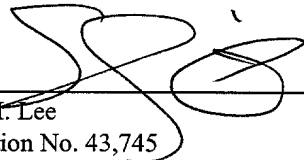
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Assistant Commissioner for Patents
Washington, D.C. 20231

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Attorney Docket No. : VENPRO.007C1

Applicant(s) : Quijano et al.

For : A BIFURCATED BIOLOGICAL
PULMONARY VALVED CONDUIT

Attorney : Sabing H. Lee

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Date of Deposit : June 28, 2000

I hereby certify that the accompanying

Transmittal in Duplicate; Specification in 12 pages; 3 sheets of drawings; **Copy of
SIGNED Declaration by Inventor in 2 pages; Preliminary Amendment in 2 pages;
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Applicant	:	Quijano et al.)	Group Art Unit Unknown
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Appl. No.	:	Unknown)	
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Filed	:	Herewith)	
)	
For	:	A BIFURCATED)	
		BIOLOGICAL PULMONARY)	
		VALVED CONDUIT)	
)	
Examiner	:	Unknown)	
)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please amend the above-identified application as indicated below.

IN THE SPECIFICATION:

At page 1, between lines 2 and 3, please add: --This is a continuation of U.S. Patent Application Serial No. 09/252,333, filed February 18, 1999.--

IN THE CLAIMS:

Please cancel Claims 1-29 without prejudice.

Please add the following claim:

30. A vascular prosthetic, comprising:

at least two valvular conduits, each of said conduits having an inflow end and an outflow end and a biological valve housed therein;

wherein each of said valvular conduits is joined adjacent said inflow ends and upstream of each of said biological valves to form a single vascular prosthetic having an

Appl. No. : Unknown
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inflow end with a cross-sectional area larger than the cross-sectional area of any of the inflow ends of said valvular conduits.


REMARKS

This application is a continuation of U.S. Patent Application Serial No. 09/252,333, filed February 18, 1999. Applicant has canceled Claims 1-29 and added Claim 30. Applicant respectfully requests entry of these amendments.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 28, 2000

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A BIFURCATED BIOLOGICAL PULMONARY VALVED CONDUITBackground of the Invention

Pulmonary valved conduits, used to replace diseased arteries such as the pulmonary artery, have been used for the last thirty years. These pulmonary valved conduits have been generally effective at treating pulmonary atresia, pulmonary stenosis, or pulmonary insufficiency. In early embodiments, the conduits consisted of crimped woven or knit polyester tubes housing a valve fabricated from metal components or metal/plastic polymer components. Later valves consisted of metal frames suspending ceramic flat or curved (convex or concave) discs or hemidisks that were passive to the flow of blood exiting the chambers of the heart.

There were at least two disadvantages of these pulmonary valved conduits. First, there was a need to preclot the polyester tubes in order to preclude blood from seeping through the pores of the knit or woven material. Second, after months of usage, a layer of fibrinous material formed in the inner lumen over time from the accumulation of blood proteins. This layer of fibrinous material, referred to as "intimal peel," often separated from the inner wall and interfered with the effective operation of the valve. An ineffective valve required re-operation to replace the conduit and valve, if caught in time. In some instances, if valve replacement came too late, the results were fatal.

In the case of a mechanical valve made of metals and ceramics, there was also the need to continuously medicate the patient with anticoagulants for the duration of his life. That is because no man-made material that is impervious to the clotting effects of blood exists today. Anticoagulation of the patient prevents coagulation of blood on the surfaces of the inner lumen and on the sinuses of the cusps of the valves. Moreover, for children suffering from congenital pulmonary atresia or pulmonary insufficiency, the use of pulmonary valved conduits were not always effective. As the child grew, the prosthetic was less effective due to its inadequate size, requiring frequent replacement. Also, for children especially, anticoagulation requirements are difficult to regiment.

Beginning in the early 1970s, biological valves were used within the crimped polyester conduits to produce a hybrid prosthetic referred to as a biological valved conduit. It was believed that a biological valve, such as a porcine aortic valve fixed with formaldehyde or glutaraldehyde, would eliminate the need for lifetime anticoagulation administration. While the desired result was achieved, there was still the problem of separation of the "intimal peel" from the inner lumen. The intimal peel clogged the leaflets of the biological valve. Moreover, while a porcine aortic valve functioned relatively well as a replacement aortic valve, where the blood pressures from the left ventricle are substantially high (80-120 mmHg), it did not function nearly as effective as a replacement pulmonary valve, where the blood pressures from the right ventricle are quite low (0-15 mmHg). The porcine aortic valve leaflets, which are relatively thick, become substantially less flexible when "fixed" by chemical solutions. Opening at low pressures becomes more difficult. Also, the flow therethrough becomes turbulent, which undesirably promotes the degeneration of the biological material.

The disadvantages mentioned above can be minimized or overcome by using a naturally formed biological conduit which integrates a valve suitable for pulmonary replacement. Preferably, the valve opens and remains open with minimal resistance to the flow of blood at relatively low pressures of less than 1 mm Hg. The valve should also preferably close under the effect of minimal backflow of blood and be capable of withstanding backflow pressures of up to 200-300 mm Hg. An example of a naturally-formed valvular conduit is described in U.S. Patent No. 5,500,014 to Quijano, et al., the entire specification of which is incorporated herein by reference.

Even this arrangement is limited in that the naturally formed donor conduits have normally minimum diameters of about 22 mm. The largest naturally occurring biological valved conduits are veins with venous valves found in the jugular veins of caprine, cervine, canine, ovine, bovine, equine and other quadruped species and marsupials (e.g., kangaroos and wallabies). While children may be treated effectively with pulmonary valved conduits having such diameters of 22 mm or less, many adolescents and adults require larger-diameter prosthetics. The flow capacity of a pulmonary conduit exiting the right ventricle must be large enough to permit

oxygenation of the blood at a sufficient rate to maintain systemic perfusion with blood returning to the heart from the lungs. With normal pulmonary circulation, the blood exiting the right heart through the pulmonary artery (trunk) divides into two separate flows: the right pulmonary artery servicing the right lung, and the left pulmonary artery servicing the left lung. That requires that each lung receive enough flow of blood through each of the two pulmonary arteries emanating from the pulmonary trunk. That flow capacity often requires a diameter greater than the 22 mm found in the jugular veins of donor animals.

Summary of the Invention

The present invention comprises a pulmonary valved conduit that permits inflow diameters greater than about 22 mm while still maintaining the advantages of a naturally-formed biological valved conduit. Specifically, the present invention comprises a vascular prosthetic suitable for replacing a patient's damaged or missing pulmonary valve, said prosthetic comprising an inflow conduit comprising a manifold formed from the sealed attachment of a plurality of donor valved blood vessels, each of said blood vessels housing a biological valve integral therewith, said blood vessels configured to permit the flow of blood therethrough by the valve opening at a relatively low pressure and configured to prevent the backflow of blood therethrough by the valve closing so as to withstand relatively high pressures, said manifold formed upstream of each of the biological valves so as not to interfere with the effective operation of the biological valves, said inflow conduit having a resulting flow capacity following sealed attachment that is larger than the original flow capacity of each of the donor blood vessels, said prosthetic also comprising an outflow conduit positioned downstream of each of the biological valves.

The present invention prosthetic is prepared by using two approximately equal sized (diameter) jugular valved veins obtained from one of the quadrupeds identified above and attaching them in such a fashion to provide a resulting inflow area larger than each of the original donor veins. The inventive manifold does not alter or disturb the configuration of the valve itself. In the preferred embodiment, a bifurcated device is created wherein each of the branches includes its own biological valve flow. Various means of attachment can be used, such as stitching with medical surgical

Brief Description of the Drawings

Figure 1 is a cross-section of a venous valvular conduit, showing the valve leaflets in an open position.

5 Figure 2 is a perspective of two section of venous valvular conduits, indicating where a proposed slicing of the conduits is to be made.

Figure 3 is a perspective of the two section of venous valvular conduits of Figure 2, indicating where the slices of the conduits have been made in preparation for attachment.

10 Figure 4 is a perspective view of the preferred embodiment of the present invention showing how the two venous valved conduits of Figure 2 have been joined.

Figure 5 is a perspective view of a variation of the embodiment of Figure 4 showing a unitary outflow end.

Detailed Description of the Preferred Embodiment

15 With reference to Figure 1, the present invention improves upon the use of a naturally-formed venous valvular conduit 10 consisting of a blood vessel 12 housing a biological valve 14. The valve 14 consists of a plurality of leaflets 16 (two shown) that easily open upon the flow of low pressure blood 18, but closely tightly against a relatively low backpressure of blood; remaining sealed even against backpressures as high as 200-300 mmHg. Such venous valvular conduits may be found, as indicated
20 above, in one of many quadrupeds. Preferably, the donor venous valvular conduit is a section of the jugular vein of a quadruped, the diameters of which approach about 22 mm. While humans have naturally-formed venous valvular conduits, none approach that diameter.

25 With reference to Figures 2-4, the present invention comprises a method of making a vascular prosthetic comprising a valvular conduit suitable for pulmonary valve replacement, wherein the conduit has a diameter greater than 22 mm. The flow output of many human adult right ventricles requires that a pulmonary valve prosthetic have diameters greater than 22 mm to maximize the effectiveness of the prosthetic. With specific reference to Figure 2, the present invention maximizes that benefit by
30 inventively combining two generally-equally-sized donor valvular conduits 20, 30, each having a biological valve 22, 32 housed therewithin. Each conduit 20, 30 has

an inflow end 24, 34 and an outflow end 26, 36. The donor valvular conduits are preferably fixed to effectively preserve the conduits in an aldehyde solution; preferably glutaraldehyde, or any other similar solution such as formaldehyde. That entails, for example, soaking the tissue in the aldehyde solution or passing the solution through the valved conduit while immersing the conduit in said solution. Other types of fixation include gamma radiation and polyepoxy compounds. In the preferred embodiment, a slice of the conduits 20, 30 is made where indicated at 28, 38.

Referring to Figure 3, the slicing of each conduit 20, 30 results in an angular sectioned inflow end 24, 34 configured to be joined in a manner shown in Figure 4. As shown in Figure 4, the resulting vascular prosthetic 50 comprises an inflow end manifold 52 having a diameter D2. Where the diameter of each donor conduit is D1, the diameter D2 of the resulting prosthetic conduit inflow end manifold 52 is greater than D1. Where it is desired to have a vascular prosthetic with an inflow end diameter greater than 22 mm, the preferred embodiment of the present method comprises attaching two donor valvular conduits having diameters substantially less than about 22 mm in the manner shown in Figures 2 and 3. The resulting diameter D2 will be greater than 22 mm.

As shown in Figure 4, the present invention prosthetic 50 comprises the inflow end manifold 52 having a seam 54 upstream of the two donor biological valves 22, 32. Preferably, to minimize the angle of transition for the blood flow 56, the slice cut from the two donor conduits 20, 30 is made at an angle (θ_1) of less than about 15°, although other angles may be appropriate. The resulting angle (θ_2) of the vascular prosthetic is, therefore, preferably less than 30°, although other angles may be appropriate. Where desired, the resulting prosthetic itself may be preserved via chemical fixation or other type of fixation.

It is contemplated that the attachment of sectioned donor conduits 20, 30 be made via a plurality of stitches made in one or more passes. Preferably, a single pass of stitches is made on the interior to maintain as smooth an inner lumen as possible. Furthermore, it is preferable that each stitch be applied in a manner that said stitches will not unravel when tissue and included neighboring stitches are severed. Discrete stitches may be used. Externally, at least one pass, but preferably two passes, of

stitches is applied to reinforce the attachment. Other methods of attachment are also contemplated, including biological and chemical sealants, and laser beam radiation.

With the embodiment of Figure 4, the inflow end 52 may be attached directly to the right ventricle at or about the location of the inflow to the patient's pulmonary trunk. Each outflow end 26, 36 of the prosthetic may be attached to the left and right pulmonary arteries, respectively, thereby bypassing the patient's diseased or missing pulmonary valve. Alternatively, each outflow end 26, 36 could be attached to different locations of the downstream end of the patient's pulmonary trunk, if desired.

With reference to Figure 5, a second embodiment 60 of the present invention is contemplated. The second embodiment 60 comprises an inflow end manifold 62 having a seam 64 and an outflow end manifold 66 having a second seam 68. Where it is desired to have a prosthetic with a single outflow end, the present inventive method further comprises slicing the outflow ends of two donor valvular conduits in the same or similar manner as described above and shown in Figure 3. Performing those steps, the outflow ends of the donor valvular conduits may be attached to form the second outflow end manifold 66 wherein the resulting seam 68 is formed from a plurality of passes of stitches, as described above. This second embodiment 60 may be attached at the inflow end to the right ventricle and at the outflow end to the pulmonary trunk, thereby bypassing the patient's diseased or missing pulmonary valve.

WHAT IS CLAIMED IS:

1. A vascular prosthetic suitable for replacing a patient's damaged or missing pulmonary valve, said prosthetic comprising:

an inflow conduit comprising a manifold formed from the sealed attachment of a plurality of donor valved blood vessels, each of said blood vessels housing a biological valve integral therewith, said blood vessels configured to permit the flow of blood therethrough by the valve opening at a relatively low pressure and configured to prevent the backflow of blood therethrough by the valve closing so as to withstand relatively high pressures, said manifold formed upstream of each of the biological valves so as not to interfere with the effective operation of the biological valves, said inflow conduit having a resulting flow capacity following sealed attachment that is larger than the original flow capacity of each of the donor blood vessels, and an outflow conduit positioned downstream of each of the biological valves.

2. The prosthetic of Claim 1 wherein said inflow conduit is configured to attach to the patient's heart to receive blood from the right ventricle.

3. The prosthetic of Claim 1 wherein said outflow conduit is configured to attach to the patient's pulmonary artery downstream of the patient's pulmonary valve that is damaged or missing.

4. The prosthetic of Claim 1 wherein the inflow conduit manifold is formed in a manner so that the angle of transition of the blood running therethrough at the inflow conduit manifold is less than about 30°.

5. The prosthetic of Claim 1 wherein the biological valves open at pressures as low as about 1 mm Hg and wherein the biological valves remains sealably closed so as to withstand backflow pressures greater than about 200 mm Hg.

6. The prosthetic of Claim 1 wherein the outflow conduit also has a manifold formed from the sealed attachment of said plurality of valved blood vessels, said outflow conduit manifold formed downstream of said biological valves so as not to interfere with the effective operation of the biological valves, said outflow conduit

having a resulting cross-sectional area larger than the original cross-sectional area of each of the blood vessels.

5 7. The prosthetic of Claim 6 wherein the outflow conduit manifold is formed in a manner so that the angle of transition of the blood running therethrough at the outflow conduit manifold is less than about 30°.

 8. The prosthetic of Claim 1 or 6 wherein the outflow conduit is configured to attach to the patient's pulmonary artery at a point downstream of the patient's pulmonary valve that is damaged or missing.

10 9. The prosthetic of Claim 1 further comprising a second outflow conduit positioned at the downstream side of the biological valves, the second outflow conduit configured to attach to the patient's pulmonary artery at a point downstream of the patient's pulmonary valve that is damaged or missing.

15 10. The prosthetic of Claim 9 wherein the first outflow conduit is configured to connect to the left pulmonary artery and the second outflow conduit is configured to connect to the right pulmonary artery.

 11. The prosthetic of Claim 1 wherein the resulting diameter of said valved conduit is greater than 22 mm.

 12. The prosthetic of Claim 11 wherein the resulting diameter of said valved conduit is greater than 28 mm.

20 13. The prosthetic of Claim 1 wherein the axial seam is made by slicing away a portion of the upstream side of each biological valved blood vessel and suturing the blood vessels together with a single pass of stitches on the interior of said blood vessels so as to maintain a relatively smooth interior lumen surface.

25 14. The prosthetic of Claim 9 wherein the axial seam is made by slicing away a portion of the downstream side of each biological valved blood vessel and suturing the blood vessels together with a single pass of stitches on the interior of said blood vessels so as to maintain a relatively smooth interior lumen surface.

 15. The prosthetic of Claims 13 or 14 wherein the single pass of stitches comprises a plurality of knots.

16. The prosthetic of Claims 13 or 14 wherein the axial seam further comprises a plurality of passes of stitches on the exterior of the blood vessels so as to reinforce the seam.

17. The prosthetic of Claim 1 wherein the biological valved blood vessels each comprise a vein segment.

18. The prosthetic of Claim 17 wherein the biological valved blood vessels each comprise the jugular vein of a donor quadruped or marsupial.

19. The prosthetic of Claim 18 wherein the biological valved blood vessels each comprise the jugular vein of a donor caprine, cervine, canine, ovine, bovine, equine or marsupial.

20. The prosthetic of Claim 1 wherein the inflow conduit results from the splicing of two biological valved blood vessels.

21. The prosthetic of Claim 17 wherein the biological valves are naturally formed within the vein segments.

22. The prosthetic of Claim 21 wherein the biological valves are venous valves.

23. The prosthetic of Claim 1 wherein the biological valves have been fixed.

24. A method of forming a vascular prosthetic that is suitable for implantation within a human to restore pulmonary valvular function, said method comprising the steps of:

extracting first and second vein segments from a biological source, each vein segment having at least one naturally formed venous valve formed therein, each vein segment further having an unvalved portion which is upstream from the at least one venous valve; and

laterally joining the vein segments along the unvalved portions thereof to form an inflow conduit having a cross sectional area that is substantially larger than the cross sectional area of either the first or the second vein segment.

25. The method of Claim 24 further comprising the step of treating the vein segments to preserve the competency of the naturally-formed venous valves.

26. The method of Claim 25 wherein the step of treating the vein comprises fixing the vein with an aldehyde solution.

27. The method of Claim 25 wherein the step of treating the vein comprises using gamma radiation.

5 28. The method of Claim 25 wherein the step of treating the vein comprises using polyepoxy compounds.

29. A method of treating a damaged or missing pulmonary valve in a patient, said method comprising the steps of using two or more donor, venous, valvular vessels spliced together to form a single vascular prosthetic having an inflow
10 portion that has a cross-sectional area larger than the cross-sectional area of any of said donor venous valvular blood vessels.

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A BIFURCATED BIOLOGICAL PULMONARY VALVED CONDUIT

Abstract of the Disclosure

The present invention comprises a pulmonary valved conduit that permits inflow diameters greater than about 22 mm while still maintaining the advantages of a naturally-formed biological valved conduit. Specifically, the present invention comprises a valved vascular prosthetic having an inflow conduit comprising a manifold formed from the sealed attachment of at least two venous valvular conduits.

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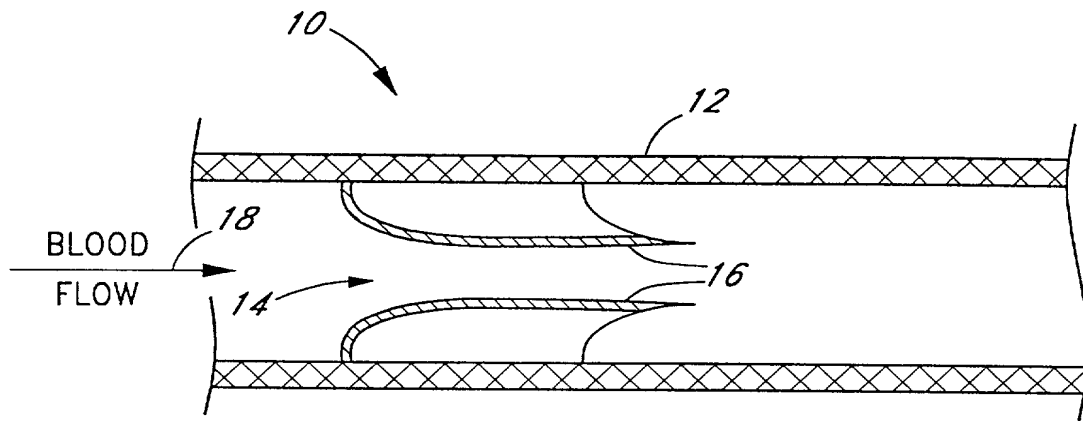


FIG. 1

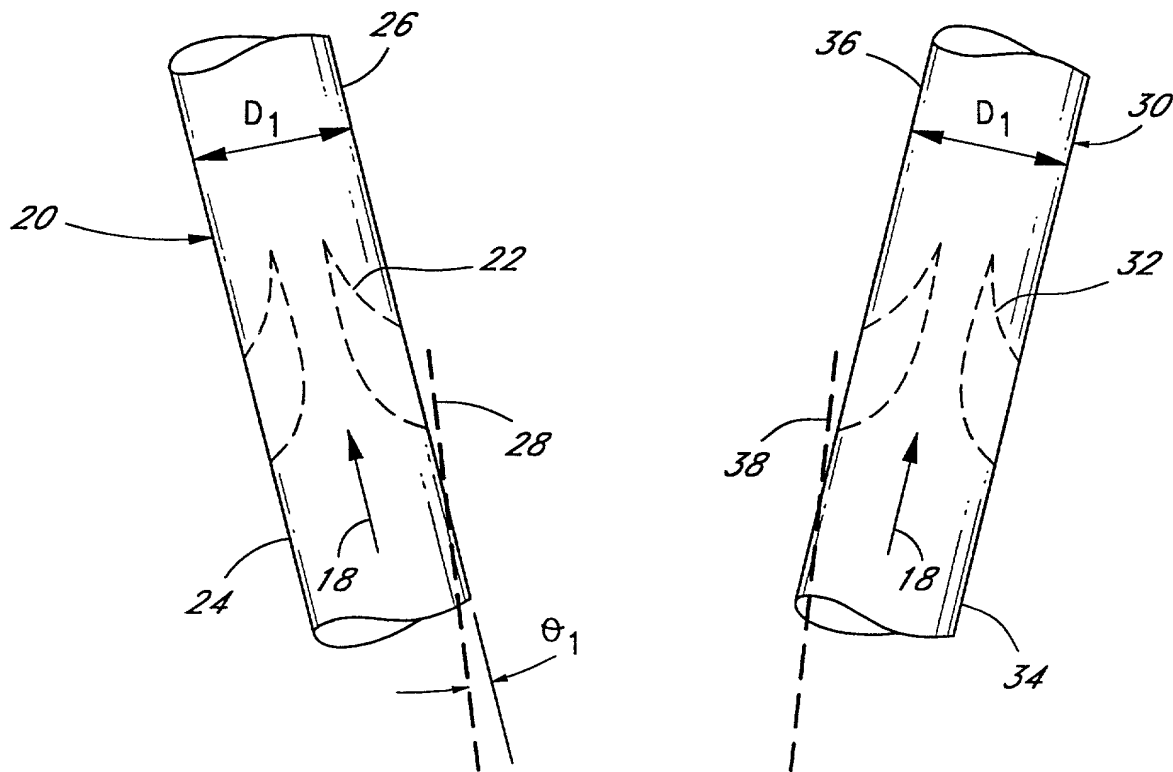
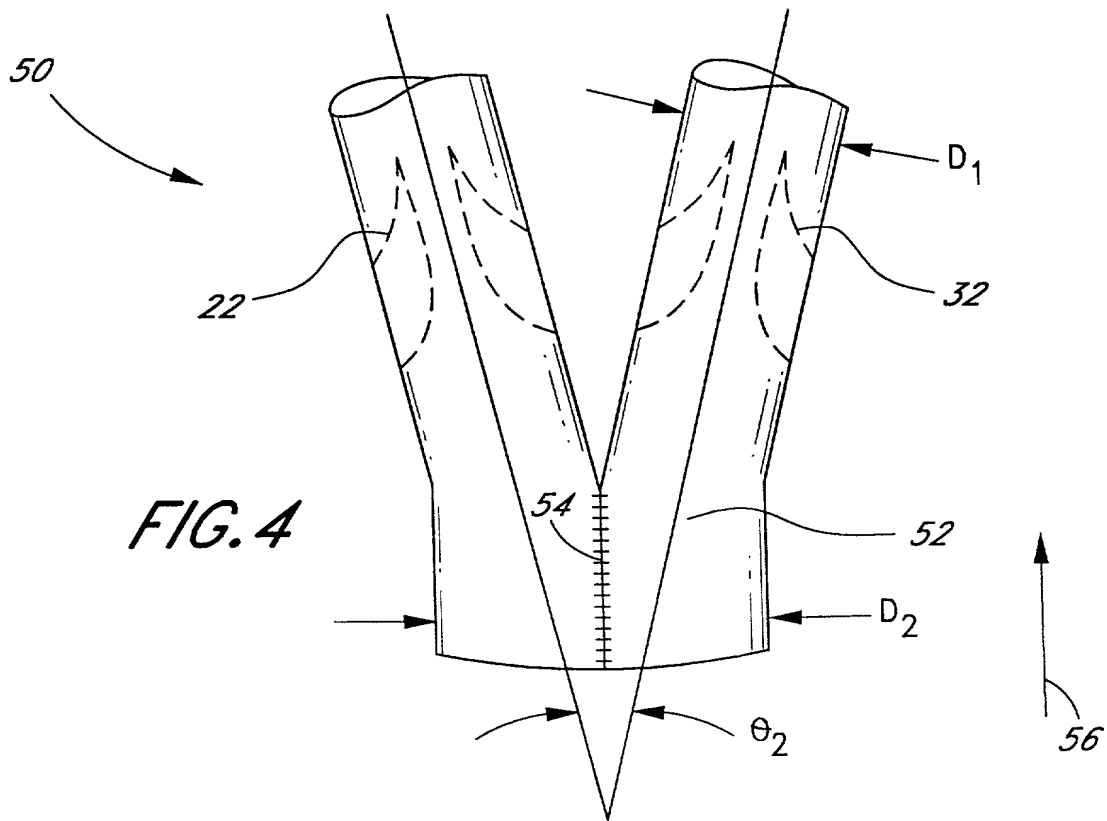
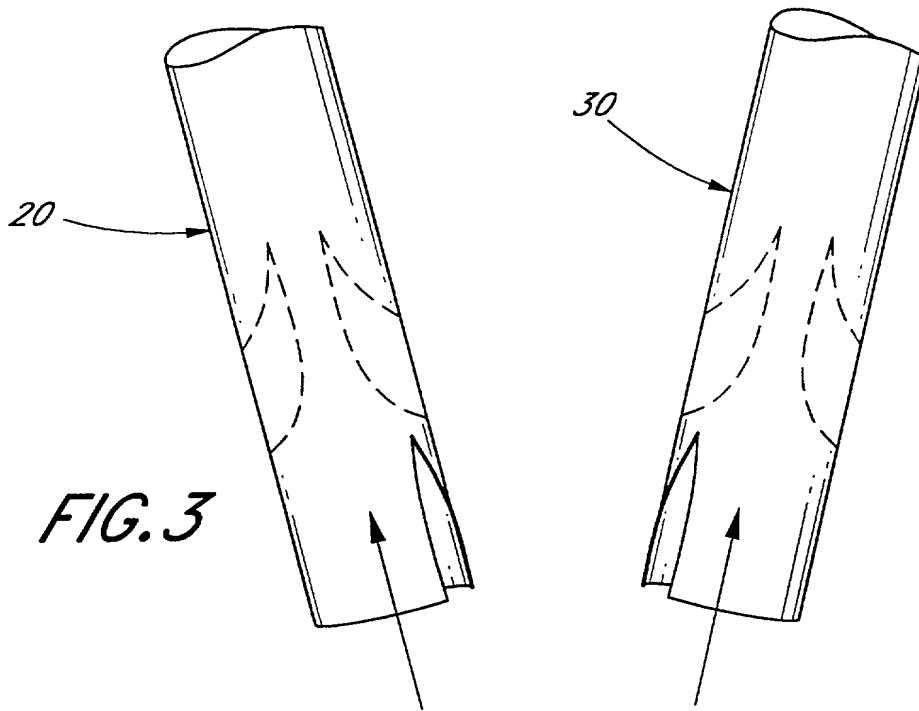


FIG. 2



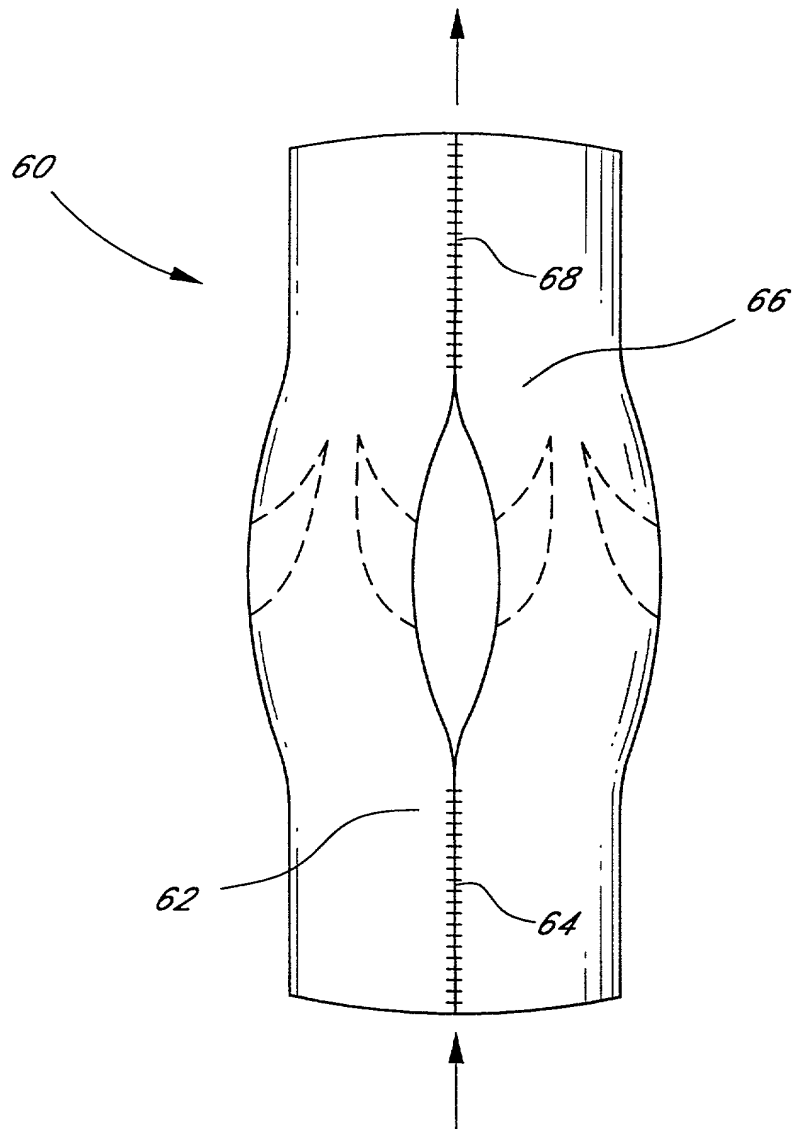


FIG. 5

DECLARATION - USA PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled **A BIFURCATED BIOLOGICAL PULMONARY VALVED CONDUIT**; the specification of which is attached hereto;

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56;

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: R. C. Quijano

Inventor's signature *R. C. Quijano*

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